Green Chemistry Alliance
Committed to Product Sustainability in the Global Economy

November 16, 2015

Ms. Barbara Lee
Director
Department of Toxic Substances Control
1001 I Street
Sacramento, CA 95814
(*via* CalSafer Web Portal)

Re: Safer Consumer Products Program Draft Stage 1 Alternatives Analysis Guidance Document

Dear Director Lee:

As you well know, the enacting legislation for the Safer Consumer Products (SCP) Program was groundbreaking in that it required a full life cycle and Alternatives Analysis (AA) regarding chemicals of concern in consumer products officially designated by DTSC as Priority Products. The alternatives analysis process is particularly significant under California's program in that it is a broad-scoped potential impact review of relevant factors associated with a chemical(s) of concern contained within a Priority Product.

Undertaking this analysis can be extremely complex and will take considerable time, resources and rigor to ensure beneficial outcomes for public health and the environment. Balancing technological feasibility, consumer acceptance and economic impacts associated with any action required by the Department of Toxic Substances Control (hereafter DTSC or Department)) based on the findings of the analysis are but some of the challenges manufacturers of Priority Products will encounter.

Section § 69505 of the SCP regulations requires DTSC to make available on its website guidance materials to "assist" responsible entities in performing AAs. In this regard, the guidance provided by the Department can be of great importance, as it will provide manufacturers with valuable insight regarding the Department's expectations when undertaking an AA. While the guidance will be helpful to those actively engaged in conducting such an analysis it will also be valuable to product manufacturers, consultant/contractors, and the general; public seeking to proactively learn from the experiences of others.

Therefore, in an attempt to assist the Department in developing this important guidance, the Green Chemistry Alliance (GCA) on behalf of its coalition members respectfully submits the following general comments regarding the *Draft Stage 1 Alternatives Analysis (AA) Guide,* released for review and public comment on September 24, 2015. Additional comments in greater detail reflecting collective input from GCA members are presented in Attachment 1 to this letter.

First, we note that this Stage 1 guidance document is not yet complete and is but the first of two documents which DTSC will develop as part of its effort to provide guidance to responsible entities which will or might be required to conduct an AA on a Priority Product. Consistent with the regulatory prioritization process, the Stage 1 guidance document describes an iterative screening process. GCA fully

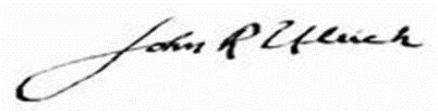
understands the nature of an iterative process aimed at reaching a decision regarding identification of alternatives to the chemical(s) of concern in the designated Priority Product that will be evaluated. However, we caution DTSC to make it clear to all who might refer to the guidance document that this iterative process is not intended to be an endless, circular and open-ended process. GCA has over the years raised the point that DTSC has been less than forthcoming regarding its most basic internal process for evaluating data and other product information. With this in mind, GCA observes that the subject guidance document is robust on the factors to be considered but deftly lacking clarity regarding its most basic process for evaluating decisions made by a responsible entity.

While we appreciate the flexibility allowed for responsible entities conducting an AA, we note the tension between the need for and value of flexibility compared with a more definitive approach that provides clarity and certainty for compliance. We had hoped the guidance would provide greater clarity in this space. At the end of the day, we appreciate the guidance and would suggest DTSC enhance the document by a more detailed description of DTSC perspectives and expectations in conducting AAs based on sound science, credible data and information that are in line with statutory and regulatory authority. In this regard, we request definitive information on what is required in an AA against what would be optional for an AA. We also urge DTSC to provide specific examples of AAs that meet DTSC's expectations, but as noted in later comments, the publically-available AA examples must conform to the same rigor and quality standards as those required of responsible entities pursuant to California law. .

As noted above, this draft Stage 1 AA Guide is not yet complete, with chapters still to be issued relating to such critical matters as Exposure Assessment and Economic Analysis. And of course, this is but one of two AA guidance documents to be developed by DTSC. Hence at this time we are unable to comment holistically on the guidance. We look forward to an opportunity to comment on the guidance for the full AA process, including approaches to presenting economic impact information in a Stage 2 AA. GCA, therefore, wishes to reserve the right to revise and extend our comments relative to Stage 1 upon thoroughly reviewing the sections still pending for Stage 1, and the Stage 2 guidance at a later time and reflecting on the interplay between the two parts. In defense of this point we refer to Table 3-1 entitled, *"A summary of potential factors requiring consideration for a two stage AA"* on page 34 of the draft Stage 1 Guide; and note that it is inconsistent with DTSC's SCP regulations (see also Attachment 1).

GCA and its coalition members appreciate your consideration of these comments and looks forward to our continued collaboration to ensure a workable, science-based program going forward. For further information or questions regarding the Green Chemistry Alliance, its members, or our comments please contact Dawn Koepke (916) 930-1993 or John Ulrich (916) 989-9692. Thank you!

Sincerely,



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ATTACHMENT 1

Distinguishing Regulatory Requirements from Non-Binding Guidance

Historically, most Alternatives Analyses (AAs) have been prepared in the context of government programs and developed by the agencies themselves or through collaborative voluntary processes with manufacturers. California's SCP program, however, is the first in the country to impose significant legal requirements on certain private parties to conduct AAs. Therefore, in preparing the Alternatives Analysis (AA) guidance document for the Safer Consumer Products (SCP) program, it is important for DTSC to clarify when it is articulating a core legal requirement and when it is presenting non-binding suggestions and recommendations intended to assist a manufacturer in preparing an alternatives analysis.

DTSC obviously recognizes this important distinction as it has included on page 2 of the draft AA Guide the following statement,

> "***Important Note:*** *This Guide is not a standard or regulation and it creates no new legal obligation. This Guide is advisory in nature, informational in content, and intended to assist responsible entities who are conducting Alternatives Analysis. This Guide does not alter or determine compliance responsibilities set forth in statutory and regulatory requirements."*

GCA fully supports this statement and strongly maintains that it not only be retained, but reiterated in other parts of the document (e.g., Appendix 1, Application of the Guide discussion on pp. 9-11). However, in other sections, of the guidance document the distinction is blurred by an inconsistency of terms. For example:

- On page 9, the document indicates that DTSC will use the document as a resource for evaluating submitted AA reports and supporting documentation. This makes the guidance document the equivalent of a regulatory requirement. Therefore, care must be taken to distinguish between regulatory requirements and interpretive guidance.

- A statement on page 10 indicates the guidance document is a "menu of options", ***not a "checklist" of required actions*** (emphasis added). Later when discussing "identification of relevant factors", the guidance document presents what it calls a "checklist" of questions. While it does not appear DTSC views this list of questions as mandatory, the use of the term "checklist" is inconsistent with the earlier choice of the term "menu" which DTSC associated with guidance rather than regulation.

- A discussion on page 42, regarding evaluation of exposure pathways states, ". . . the responsible entity ***needs to understand*** (emphasis added). not only the hazard of the chemicals, but also where the chemicals might partition into the environment when they are potentially released, how long they remain there, and how and where exposure occurs during the use phase and other life cycle phases." The statement that responsible entities "need to understand" this information is language that appears to impose a legally binding obligation.

There are other examples where the AA guidance document has used language that can imply legal requirements where they do not exist and which may not be intended by DTSC. **GCA**

recommends that DTSC review the terminology used in this document, particularly in the latter sections of the document, to make sure that the intended distinction between mandatory legal requirements and non-binding recommendations is maintained. It may be advisable, for example, to use a consistent set of terms (e.g., "shall" or "must" for legal requirements; "may" or "could" for recommendations) throughout the document, which will help readers better understand the intent of the AA guidance document.

Cost Efficiencies Related to the AA

Given the robust nature of the AA process and associated requirements, it is not surprising the guidance document would suggest the need for a responsible entity to have in-house or contract expertise in a variety of disciplines from chemistry to engineering to life cycle thinking, public health and more. That said, such expertise – whether in-house or by contract – will come at a significant cost to responsible entities. While the list of available resources is a helpful starting point, such resources merely touch the surface when considering the level of analysis a responsible entity might need to undertake even with data derived from such sources. For this reason, DTSC might consider expanding upon the suggestions within the guidance document related to establishing an AA team and the use of available resources. For small and medium enterprises (SMEs) who might not have the in-house sophistication to perform an AA, additional guidance regarding ways responsible entities might cost effectively approach the AA requirements might prove to be very useful.

Non-Alternatives Analyses Pathways

Under the SCP regulation, a responsible entity has a number of options including the option to avoid conducting an AA based on particular factors and decisions. We urge DTSC to enhance the Stage 1 guidance document to provide clarity at the outset regarding these options. More specifically, Section § 69505.2 of the SCP regulations provides for removal or replacement notifications in lieu of conducting an AA. Importantly, utilizing this mechanism is accompanied by an extensive information requirement under a compressed time frame of 90 days. As has been discussed at length over the years, the supply chain for many products is extensive, and because the regulation does not contemplate an opportunity for an extension, responsible entities may be challenged to complete the various certification requirements in order to qualify for this alternative path. We urge DTSC to include procedures for developing and applying the removal or replacement mechanism. It would be helpful therefore to alert responsible entities of the very tight time constraint.

Responsible entities also have the option under Section § 69503.5(c) of submitting an AA threshold notification in lieu of an AA. Responsible entities considering this option may use it as an approach to address product contaminants. As defined in the regulations under Section § 69501.1(a)(26), a "contaminant" is a chemical that is not an intentionally added ingredient in a product and that may be present in a product from one of several sources. Contaminants, often found at extremely low levels, can be present in many products. For products with complicated supply chains, these contaminants can have multiple entry points, over which manufacturers do not always have complete control.

The AA guidance document, at pp. 27-28, indicates that a chemical of concern present in a product as a contaminant "does not directly contribute to the function or performance of the product" and thus cannot be identified as a "necessary" part of the Priority Product. The implied presumption of this discussion is that a chemical of concern present in a product as a contaminant can always be eliminated or reduced. This may not actually be true as a practical

matter, particularly where the chemical is present at low concentrations. ***As a key consideration in the guidance document, DTSC should more fully describe its approach to this situation.***

- The question of whether a chemical of concern contaminant can be removed from a product will be a factual question to be evaluated and determined on a case by case basis. For purposes of the AA guidance document, however, it is important for DTSC to clarify which regulatory mechanisms should be used to address this issue. At least one option available under this section of the regulations includes DTSC setting an Alternatives Analysis Threshold for a chemical of concern that is part of a Priority Product. This threshold would be established as part of the rulemaking in conjunction with the listing of a particular Priority Product. Where a chemical of concern is present as a contaminant, the threshold would at least be the Practical Quantitation Limit (PQL) of the chemical of concern, but the regulations clearly authorize DTSC to set a higher threshold. Once an AA threshold has been established for a Priority Product, a manufacturer may file under Section § 69505.3 an Alternatives Analysis Threshold Notification that qualifies it to comply with the threshold limitation in lieu of conducting an AA.

GCA urges DTSC to clarify whether both only one of these options will be are available to responsible entities as mechanisms for addressing chemical of concern contaminants present in a Priority Product. ***It is particularly important that DTSC clarify this point as soon as possible since Option 1, the Alternative Analysis Threshold (AAT) option, can only occur during the rulemaking process pursuant to Priority Product listing.*** This document should include information on how the AAT would be used in an AA. Once the regulation officially listing a particular Priority Product is adopted, Option 1 is no longer available.

Meaning of "Iterative Assessment" under SCP Regulations

The AA Guide indicates in several sections that alternatives analysis is an "iterative" process. As noted, GCA finds significant value in the flexibility afforded by such an approach. We do however, remain concerned with the implications of such iterative character for transparency associated with DTSC's decision making process and the inability of responsible entities to anticipate decisions. The process for developing an AA under the SCP regulations, however, is "iterative" only in a limited way (i.e., the two stages specified in Sections § 69505.5 and § 69505.6). The suggestion in the AA guidance document that responsible entities bear an obligation for ongoing iterative analysis is confusing and ultimately inconsistent with the procedures associated with AAs in the regulations.
In the extreme this iterative character implies an open-ended process that can reconsider judgments at any time – potentially even on after an AA (either Stage 1 or Stage 2) has been accepted. That is not consistent with our understanding of either the laws or the SCP regulation.

The SCP regulations create a structured framework made up of only two stages. There are distinct obligations that attach to the two stages. A responsible entity is allowed to revisit Stage 1 determinations in the Stage 2, but the decision to do so is discretionary with the responsible entity. ***The regulations do not establish an open-ended obligation for "iterative" analysis. Accordingly, DTSC should edit the AA guidance document to remove statements that suggest such an obligation.***[1]

[1] An example of such language is the statement on p. 34: "Identifying relevant factors is an iterative and dynamic process the responsible entity conducts throughout the AA."

Guidance Table 3-1 Inconsistent with SCP Regulations

The regulations for a First Stage AA under Section § 69505.5 require a responsible entity to address the following topics:

- The functional, performance and legal requirements of the Priority Product;
- The role of the chemical of concern in meeting those requirements;
- Identification of alternatives to the Priority Product to be considered;
- The relevant factors to be used to compare the Priority Product and alternatives; and
- An initial evaluation and screening of alternatives against certain health and environmental parameters.

In addition, the responsible entity may include in the initial evaluation any other considerations identified for a Second Stage AA, including cost and economic impact. In the Second Stage AA under Section § 69505.6, the responsible entity is required to address the following topics:

- Adding to the list of relevant factors for comparison (a) the useful life of the Priority Product and its alternatives; and (b) the economic impact of the Priority Product and its alternatives;
- Evaluation and comparison of the Priority Product and its alternatives with respect to each relevant factor; and
- Decision to retain the Priority Product or to select an alternative.

Table 3-1 on page 34 of the AA guidance document does not reflect the SCP regulations, and thus is fundamentally misleading. As noted above, the regulations are clear that the Stage 1 AA is required to address the functional, performance and legal requirements of the Priority Product, as well as the role of the chemical of concern in meeting those requirements. The Stage 1 AA also identifies the alternatives to the Priority Product that will be considered. Table 3-1 inaccurately, suggests that these factors are only addressed in a Stage 2 AA. Table 3-1 is further misleading in that it blurs the distinctions between how relevant factor identification and comparison of alternatives occurs in a Stage 1 and Stage 2 AA under the regulations. ***DTSC should eliminate Table 3-1 or revise it to track the actual regulatory obligations.***[2]

Expectations for Identifying Potential Alternatives

As provided in the enacting statute and SCP regulation, responsible entities are required to review a host of potential impacts associated with the chemical of concern and potential alternatives. In several places in the AA guidance document and in the SCP regulations, the scope of potential alternatives the responsible entity may consider is defined quite broadly. If the initial scope of alternatives is broad, then there must be a corresponding way to quickly narrow the list of alternatives in the Stage 1 AA, as an intensive evaluation of many alternatives is not possible even for the largest of manufacturers. If the alternative does not address the appropriate and necessary performance needs of the priority product, there should be no further requirement to evaluate it going forward. The potential alternatives that move forward for evaluation in the Stage 2 analysis should include only those that meet the performance and functional needs of the product, not just those that have no adverse impacts. Further, alternatives which are prohibitively expensive

[2] It should be noted that the AA Guide, starting on page 15, provides a more accurate summary of the regulatory framework for the AA requirement. DTSC should consider whether this earlier section in the document is sufficient or could be upgraded to describe more specifically the required elements of the First Stage AA.

should not be considered. Of note, the enacting statute provides for consideration of reduction in adverse impacts as an option – not just elimination of impacts.

GCA therefore recommends DTSC clarify that it is logical and reasonable to use practical information (function, performance, legal requirements, relative expense, global availability, etc.) to screen alternatives before moving to deeper analysis; and that inadequate product performance characteristics, as but one example, may be used at the outset to disqualify a potential alternative.

Requiring New Information for AAs

GCA urges DTSC to provide insight within the guidance document about any "new information" that may be required and to what extent such a requirement would be pushed forth during the Stage 1 of the AA process.

In Chapter 4 on Impact Assessments, the AA guidance document addresses an important question that is likely to arise in many AAs – how to conduct scientifically sound risk and hazard assessments when there are significant data gaps on specific chemicals.[3] The primary approach taken in this section is to identify a wide range of databases and tools that could be used to assist an evaluation.

While this information is useful, DTSC should consider identifying principles that scientists typically use to identify sources of information that warrant greater weight in an evaluation. Not all information carries the same scientific standing, and that point should be recognized in the AA guidance document. We note in this regard, for example, the Green Chemistry Hazard Trait Regulation adopted by the Office of Environmental Health Hazard Assessment (OEHHA) pursuant to the SCP's authorizing statutes. This regulation draws explicit distinction between types of scientific evidence deemed "strong" in indicating the presence of a given trait, versus evidence that is merely "suggestive." Such distinctions should be taken into account by DTSC.

GCA therefor suggests that these be taken into account with respect to classifications incorporated into AAs, and further recommends that DTSC include the following principles in the AA guidance document:

Adopt an Order of Preference for Toxicology Data –c – specific information on the chemical being assessed should be used to the extent possible, before turning to broad assumptions or models.

- ***Use the Most Up-to-date Information*** - the preparer of an AA should survey data sources to determine if more current data are available.

- ***Recognize Variations in Toxicity among Chemicals in Common Categories*** - measured data on a chemical of interest should be given greater weight than a categorical label or other kinds of classification ranges.

- ***Rely on Scientifically Established Analytical Tools*** The extent of peer review and scientific validation of particular assays or modeling techniques are important indicators of the reliability of such approaches

[3] See pages 50-58 of the AA Guide.

- ***Weigh All Factors Related to Impact*** - To avoid the potential for regrettable substitution, the AA should look broadly at a chemical's impact.

GCA believes the above principles should be referenced in the AA guidance document to responsible entities with potential criteria to guide their use of the various databases, literature sources, models and tools identified in the guidance document. We believe these principles are responsible neutral practices that will improve the quality of impact assessments.

Relevant Factor Considerations

- **Market Based Factors** – The Stage 1 guidance should specifically allow for consideration of market based issues (cost, consumer acceptance). While DTSC staff suggests cost issues could be provided by the responsible entity in Stage 1 and 2 to screen out alternatives, the Stage 1 guide does not explicitly state this and should be revised to be clear on this point.

- **Exposure Factors** – GCA believes exposure factors need greater attention in the guidance document, and awaits receipt of the Exposure Assessment chapter. It is appropriate to note here, though, that the SCP explicitly states the purpose of the AA to be *"determine how best to eliminate* ***or reduce potential exposures to****, or the level of potential adverse impacts posed by*" chemicals of concern (emphasis added). The present draft, however, seems to betray a bias toward removal, and on page 29, seems indeed to contradict the SCP in stating that: "*a principal goal of the SCP regulations is to remove a Chemical of Concern that is not needed for the product function or performance.*" While we recognize that the current DTSC regulatory structure is based upon hazard elimination, DTSC must consider more than mere presence of chemicals in products.

- **Exposure Pathways** – The guidance allows for the use of conceptual models to depict interactions with exposure pathways; however, DTSC and responsible entities should tread carefully as conceptual models are not necessarily science based rather often merely provide an educated guess. T***he exposure pathways element of the AA process should require a consistent level of rigor, which DTSC can ensure through more clear direction to responsible entities.*** This is particularly important to help avoid regrettable substitutions and we urge attention to this in the upcoming Chapter on Exposure Assessment.

- **Material Difference and Material Contribution** – On pp. 16 and 33, Step 3 discusses "material difference and material contribution" as part of what are considered relevant factors for AAs; however, the explanation of these terms on page 33 are somewhat vague. DTSC should provide examples to better clarify how a responsible entity might make these judgments in the AA and whether/how these terms create a yardstick for compliance or acceptability of the information submitted.

- **Confidential Business Information (CBI)** – The SCP regulations discuss CBI issues in depth; however, the guidance document is silent on CBI process and considerations beyond its applicability to proprietary research on page 56. As an example, page 17 of the Stage 1 guidance document notes that the DTSC will make the final AA report publicly available for review and comment prior to making its determination about the report, but does not include mention of CBI process and consideration. ***We urge DTSC***

to reference the CBI provision, even if more detail is contemplated for the Stage 2 guidance document.

- **Research and Development** – In the guidance document's discussion of "Abridged AAs" (pp 19-20) it makes clear that if an alternative cannot be identified that the Department will issue a "regulatory response" determination for the priority product which at a minimum will require the responsible entity to provide product information for consumers and conduct an R & D project or fund a challenge grant to seek and make available a safer product to replace the priority product. The DTSC regulations are silent on these thorny issues. GCA urges **DTSC to revise its guidance to provide greater clarity and detail about these requirements and DTSC's expectations.**

- **List of Factors and Endpoints (Appendix 3-1)** – For toxicity endpoints in particular, tiered testing approaches make screening processes like this more rational, cost effective and less animal resource intensive. In this regard, DTSC should reference such approaches as part of its guidance.

AA Consistency & Rigor in Data & Supporting Information

As noted, GCA supports the flexibility the guidance document suggests for responsible entities in making fundamental judgements. This affords larger, well-resourced entities the opportunity to utilize their internal resources, processes and expertise – something we appreciate and greatly value. However, we remain concerned about the ability for smaller responsible entities to undertake these requirements.

And While we appreciate the resources suggested for responsible entities within the guidance document that begin to speak to resource issues particularly for those smaller entities, many of these resources have originated from chemical advocacy non-governmental organizations. This is concerning in that some of their tools, like ChemSec's "SIN List," purport to be scientifically based, but incorporate some exceptions in deference to public controversy. This raises the question of whether such services or "publicly available" AAs will be required to meet the same demands for rigor in documenting the specific judgements behind their conclusions and tools that other responsible entities will have to meet when submitting original supporting material.

We note that during its webinar discussion on the draft AA guidance document DTSC made a point of emphasizing that the Department will not engage in offering recommendations to responsible entities seeking consultant/contractor assistance to prepare their AA(s). However, it is inconsistent that the guidance document itself iterates many organizations offering lists, tools or processes to which responsible entities can turn. Such inclusion imply endorsement of those offerings, many of which must be contracted

It is clear that many smaller responsible entities and their contractors would welcome lists of supporting information and tools such as these lists. However, to the extent the organizations, their tools and services are outside the realm of recognized government agencies or authoritative bodies, the listings should simply be just that – lists – with no embellishment implying DTSC endorsement.

DTSC should also provide clarification regarding the level of rigor and documentation to which such services and publicly available AAs will be subjected upon review. A lack of consistency in rigor and documentation would inappropriately result in differential standards being used as a tool to achieve contracted AA as compared to an AA prepared in-house by a responsible entity.

GCA urges DTSC to clarify the level of rigor in data and documentation for all entities – regardless of who generates the data and information. Responsible entities, whether preparing AAs in-house or through contract services, must meet the same requirements. Final AAs must not be allowed to be inappropriately leveraged in the market based on a regulatory response DTSC may impose that is disproportionate between a responsible entity's in-house AA and an AA developed by a public or contract services, or between two or more responsible entities regardless of who prepares the AA. Consistency and scientific rigor must be applied across all AAs

Clarification of AA Review and Determination Criteria

As previously noted, we remain concerned about the iterative nature of the AA process and other stages of the SCP Program. We urge DTSC to address the lack of clarity about how itwill make various decisions including review and determinations associated with review of AAs and their diligence in reviewing the relevant factors and substantiating those that were determined not to be relevant. Under Section § 69505.9 of the regulations, there are a mere three criteria by which DTSC is required to judge compliance with the requirements including:

a) Whether the report was submitted in a timely fashion;
b) Whether and to what extent the responsible entity considered and addressed all of the applicable provisions pertaining to the preparation and submittal of the AA report; and
c) Whether and to what extent the responsible entity demonstrated the conclusions of the AA were based on "reliable" information.

GCA urges DTSC to provide greater insight into how it will evaluate responsible entities' compliance when reviewing AA submittals.

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